

# Patient Controlled Dispenser & Deactivator of Liquid Oral Pain Medication

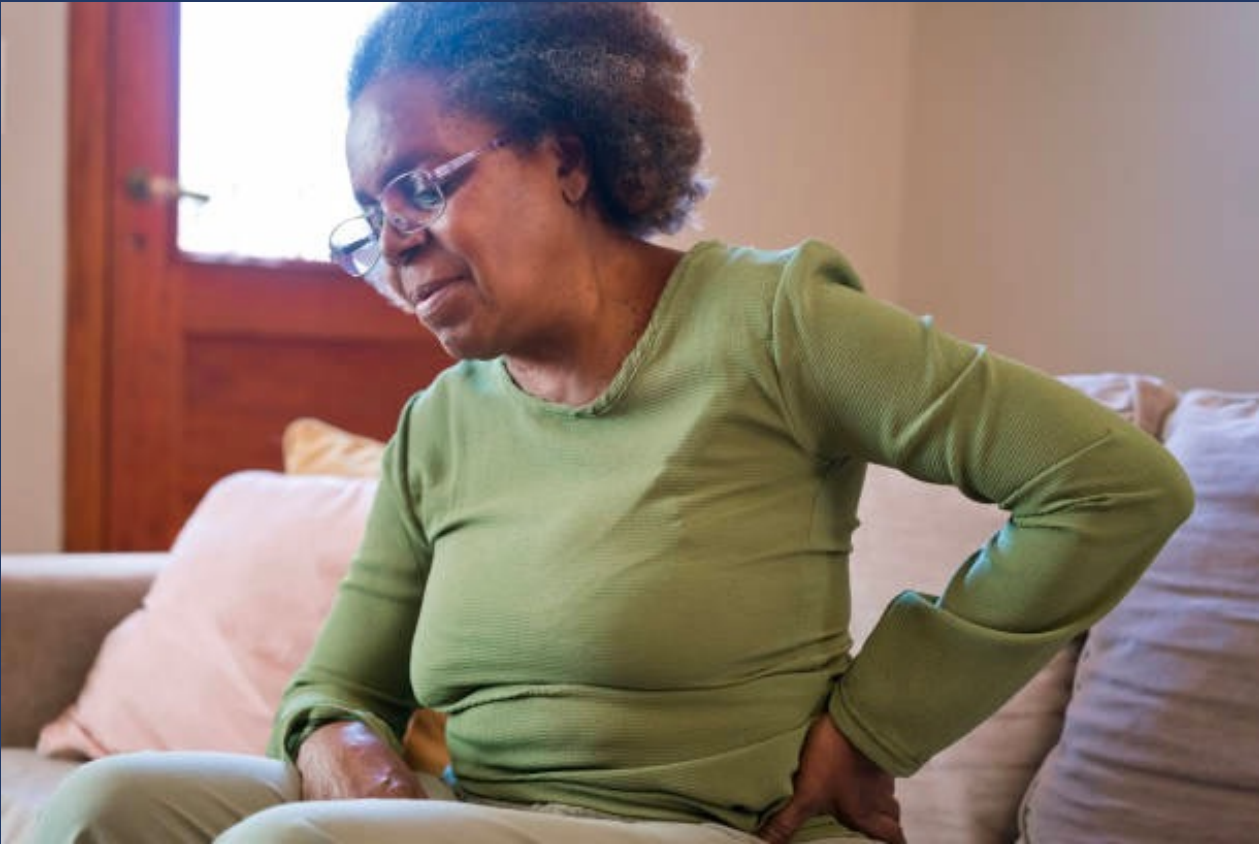


PCDD

Empowering Patients  
with a Sip

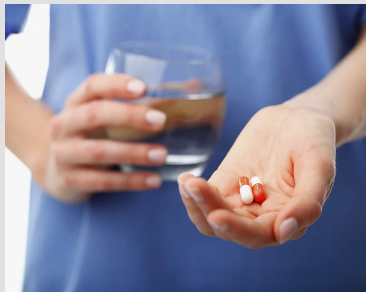
[jinglei.li@yale.edu](mailto:jinglei.li@yale.edu) | [daniel.wiznia@yale.edu](mailto:daniel.wiznia@yale.edu) | [claudia.see@yale.edu](mailto:claudia.see@yale.edu)

# Pain Management: A Universal Issue



# The Problem: 100 million patients need postoperative pain control, but current modalities are flawed

## Nurse-Dispensed Pills



Staffing costs

Opioid diversion

## Intravenous (IV) Patient Controlled Analgesia (PCA) Pump



Invasive

Not indicated for most patients

## Pill PCA



Side effects

Opioid diversion

# Co-Founder Team



**Jinlei Li, MD, PhD FASA**

- YSM Associate Professor
- YNHH Director of Regional Anesthesia
- Nationally known Acute Pain Expert
- Inventor of Yale Cocktail



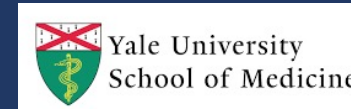
**Daniel Wiznia, MD, FAAOS**

- Yale Assistant Professor of Orthopaedics and Mechanical Engineering
- Former McKinsey Consultant
- Quik-Clot / Z-Medica startup



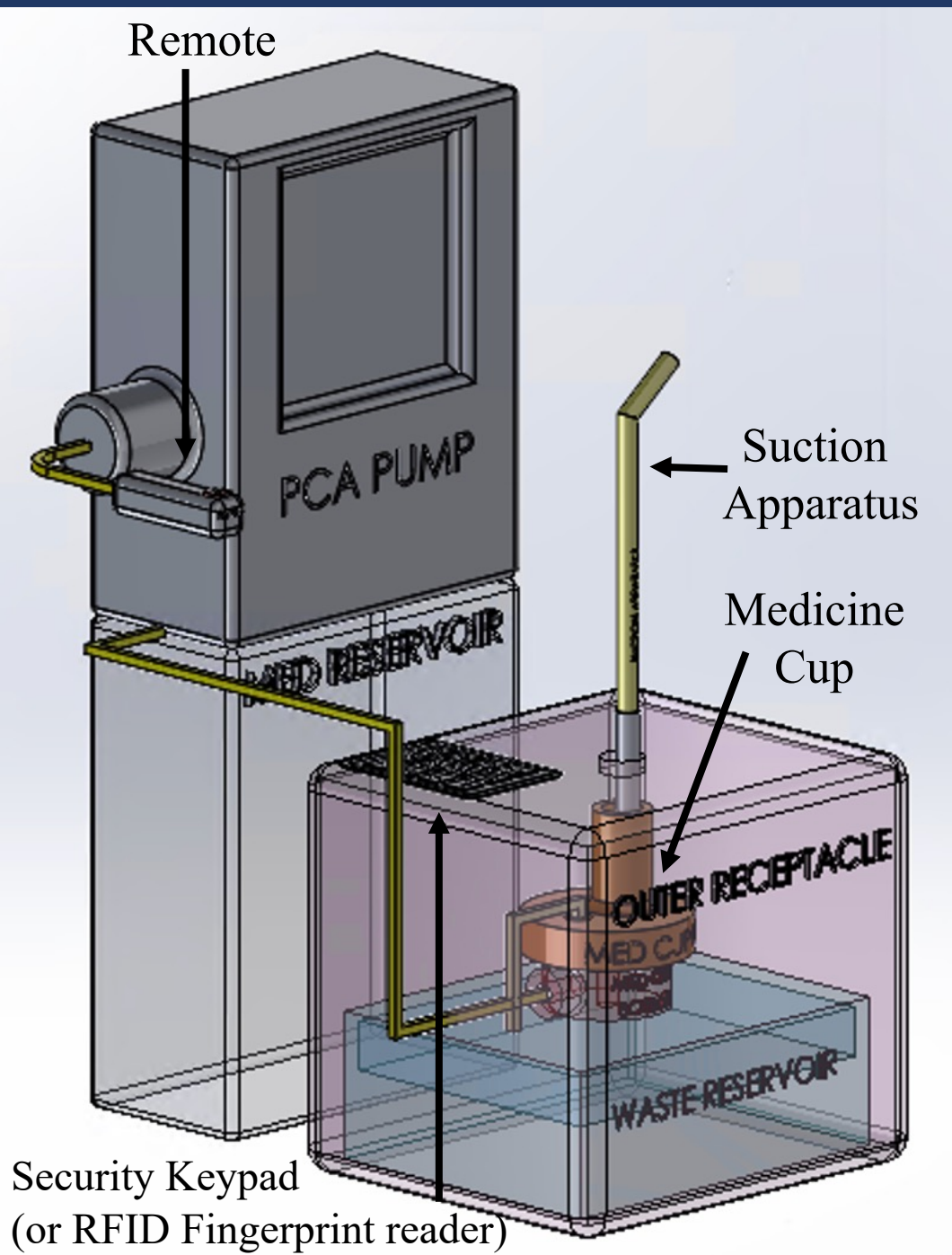
**Claudia See, BS**

- 4th-yr MD-MBA Student at Yale ('24)
- Former R&D Engineer at Medtronic
- Yale College '17 (BS in Biomedical Engineering)



**Advisors:** Yale Ventures, Yale Center for Clinical Investigation, Saul Ewing Arnstein & Lehr LLP, regulatory consultants





# How It Works

## Steps:

- 1) Patient will press a button to dispense a dose.
- 2) The PCA pump will pump this dose into the medicine cup.
- 3) The patient will be able to drink this dose by sucking out of a straw.
- 4) Any excess medicine left over will be deactivated in the waste reservoir using activated charcoal & solidifier.

# PCDD Revolutionizes Pain Management

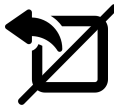


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Personal: Only unlocks with patient's RFID fingerprint



Safe: Eliminates need to return unused medicine



Customizable: Smaller dosing at higher frequency



Trackable: Real-time remote monitoring of consumption

# Patients and Nurses Prefer Medication on Demand



**Patients**

"I prefer to use this device because I am an independent person."

"For my c-section, I was pleased with my PCA. I did not have to call and it was there."

- 57% called nurse for pain meds 4-6x daily
- 34% receive delayed medicine
- 71% would prefer or be interested to try PCDD



**Nurses**

"Change of shift is when patients can wait 1 hour for medicine."

"All we do is pass pain meds."

- 47% of their time is spent managing pain
- Rate PCDD 6.4 out of 10 over pills

# Many Organizations Value PCDD





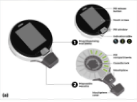
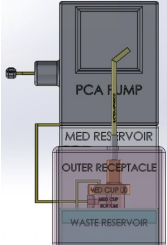


Opioid Diversion Committee and Stewardship Committee  
Patient Family Advisory Committee  
Pharmacy Investigational Drug Service





# PCDD's Novelty is Safe, Cost-Effective Delivery of Liquid

Category	Product	Low Nurse Staff Requirement	Low Cost (compared to IV pump)	Ease of Use	Patient Pain Control Satisfaction	Diversion Control (compared to pills)
Nurse Dispensed Pills	 NA; Standard of Care		✓			
PCA Pump	 CADD-Solis: Traditional IV Pump			✓	✓	
Pill PCA	 PCoA Acute (Dosenrx)	✓	✓	✓		
	 Avancen Corporation Medication on Demand (MOD)	✓	✓	✓		
	 ReX (Dosenrx)	✓	✓	✓		
Liquid PCA	 PCDD	✓	✓	✓	✓	✓

# User Friendly App Interface

Welcome to  
PCDD



Here's how much  
medicine you have  
taken so far:



Please select your  
pain level to receive  
a titrated dose.

Pain Level		Dose
😊 0	→	0 mL
2	→	5 mL
4	→	10 mL
6	→	15 mL
8	→	20 mL
☹️ 10	→	25 mL

**ALERT!**

We've noticed you  
have rated 10/10 pain  
over the last 2 doses.

Our team would like  
to adjust your dosing.

Call Us:  
**888-888-8888**

Dose has been  
dispensed!

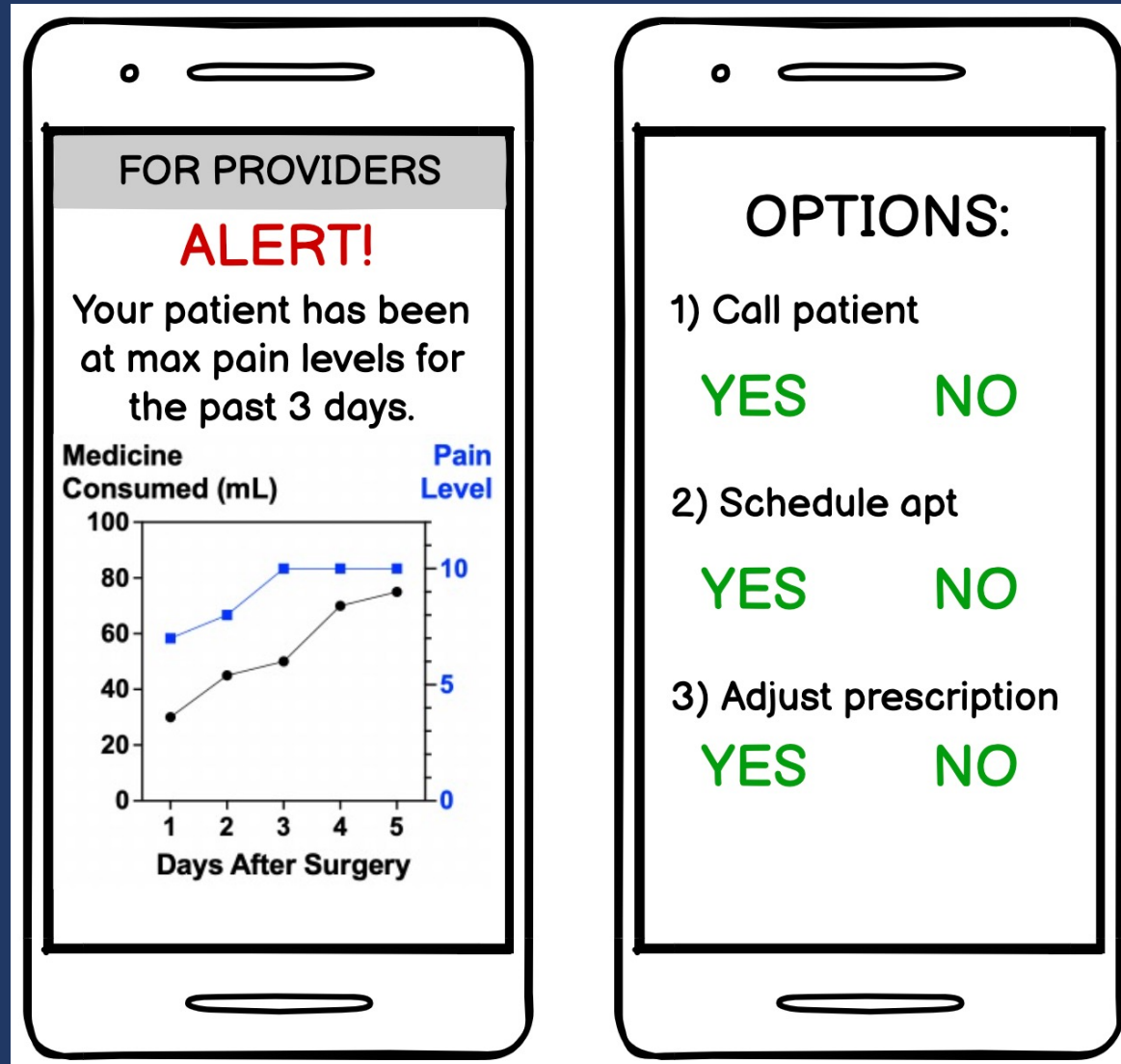
Please provide your  
fingerprint to unlock  
the straw and sip your  
medicine.



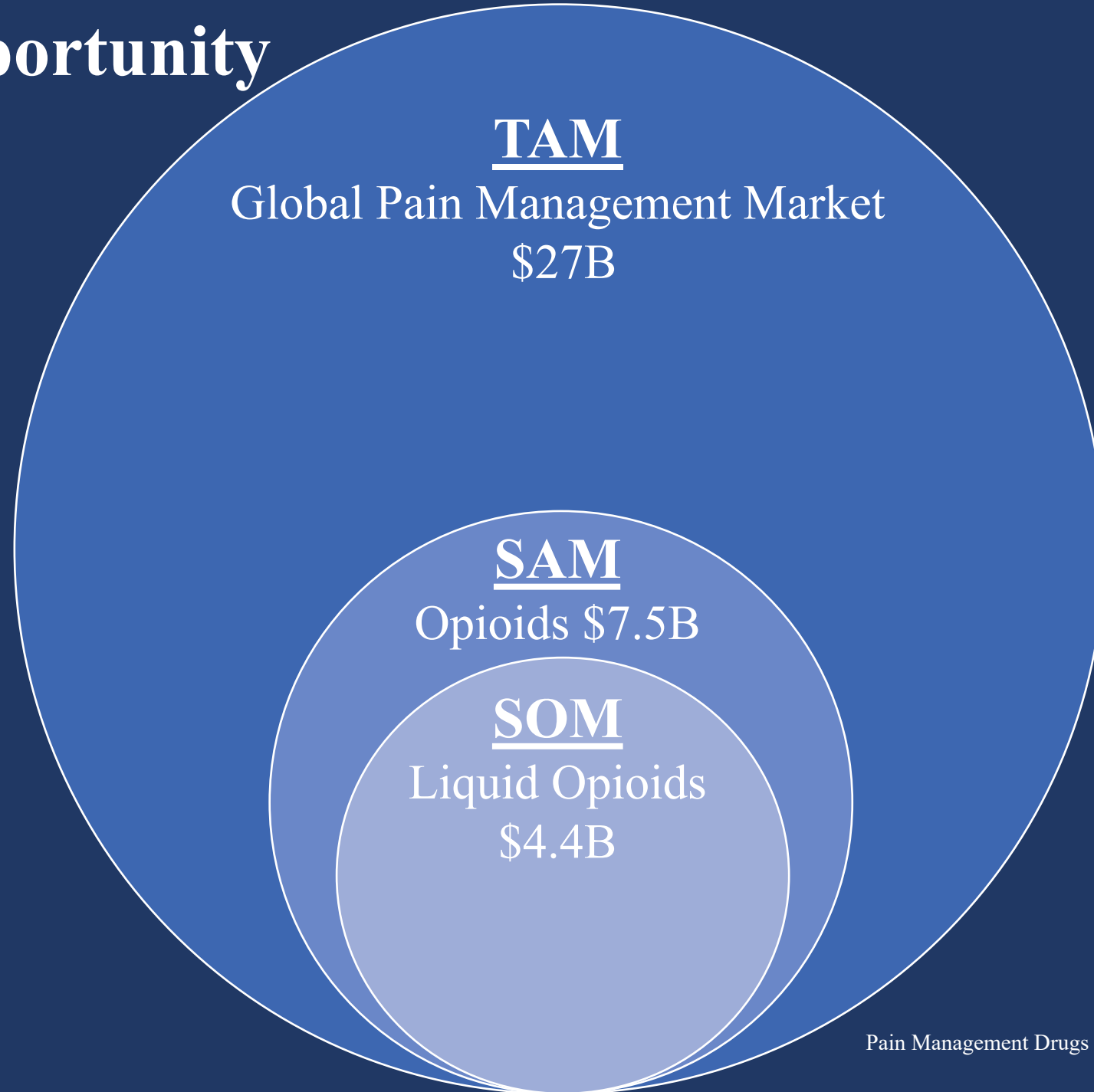
Your next dose will be  
available in 2 hours  
at 4:00 PM

# Remote Home Monitoring Data

- 1) Real-time opioid consumption data are continuously sent to both patients & physicians
- 2) Physicians can remotely modify prescriptions based on patient needs



# Market Opportunity



- Beachhead Market:**  
Surgical patients who need high dose opioids for 12+ hours.
- Orthopedics
  - Trauma
  - General surgery
  - Surgical oncology
  - Cardiothoracic

# Unit Economics Show \$1M Savings with 380 Patients

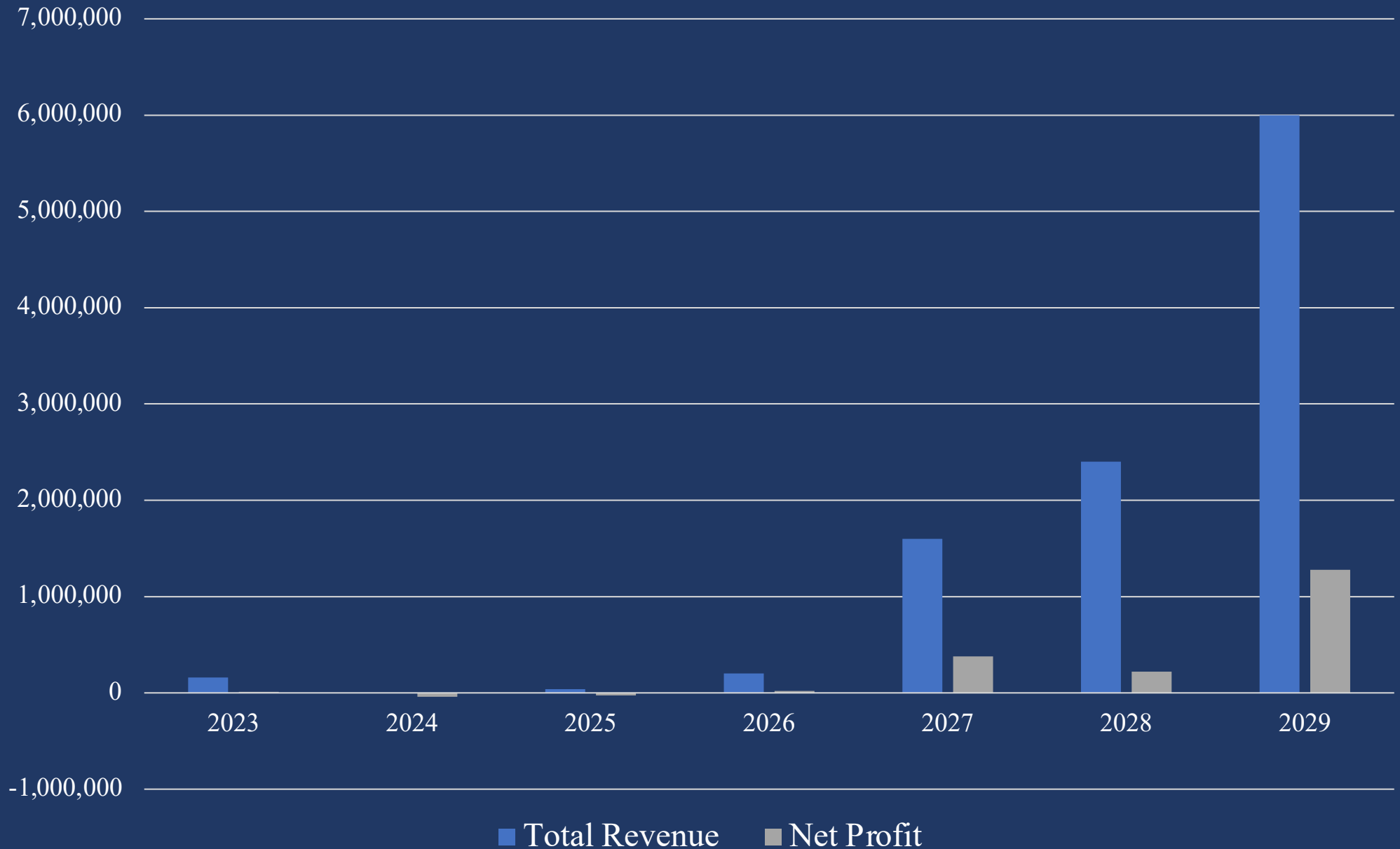
Each PCDD saves ~\$2,634 or 35% compared to pills



	Hospital Stay	Nursing	Pharmacy	Medicine	Unit Device Cost	Patient Satisfaction	Risk of Increased Healthcare costs	Overhead Costs	Total
Pills (Status Quo)	\$4.4K	\$1.3K	\$60	\$10	\$10	n/a	1.28x	\$50	\$7,463
PCDD	\$3K	\$900	\$300	\$30	\$300	4%	n/a	\$500	\$4,829



# Financials: PCDD to Earn \$1.2M in 2029 Across the Northeast



# PCDD to Launch at YNHHS in 2025



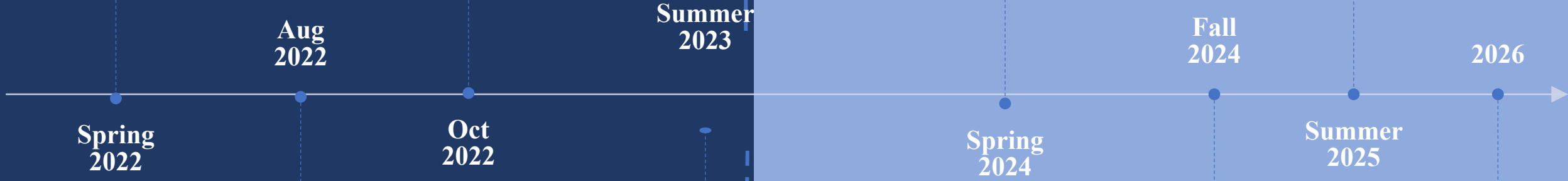
American Society of Anesthesiologists®

- Filed 2 provisional patents  
- Built 3 prototypes  
- Interviewed customers

Swimming with Sharks Award from ASA

**\$30k Blavatnik Award**  
- YNHH clinical trial  
- FDA Investigational Device Exemption & 510k submissions

YNHHS device launch



**\$150k**  
YNHHS Innovation Award

- n=30 build with contract manufacturer  
- Filed utility patent  
- Yale SOM Award for Entrepreneurship

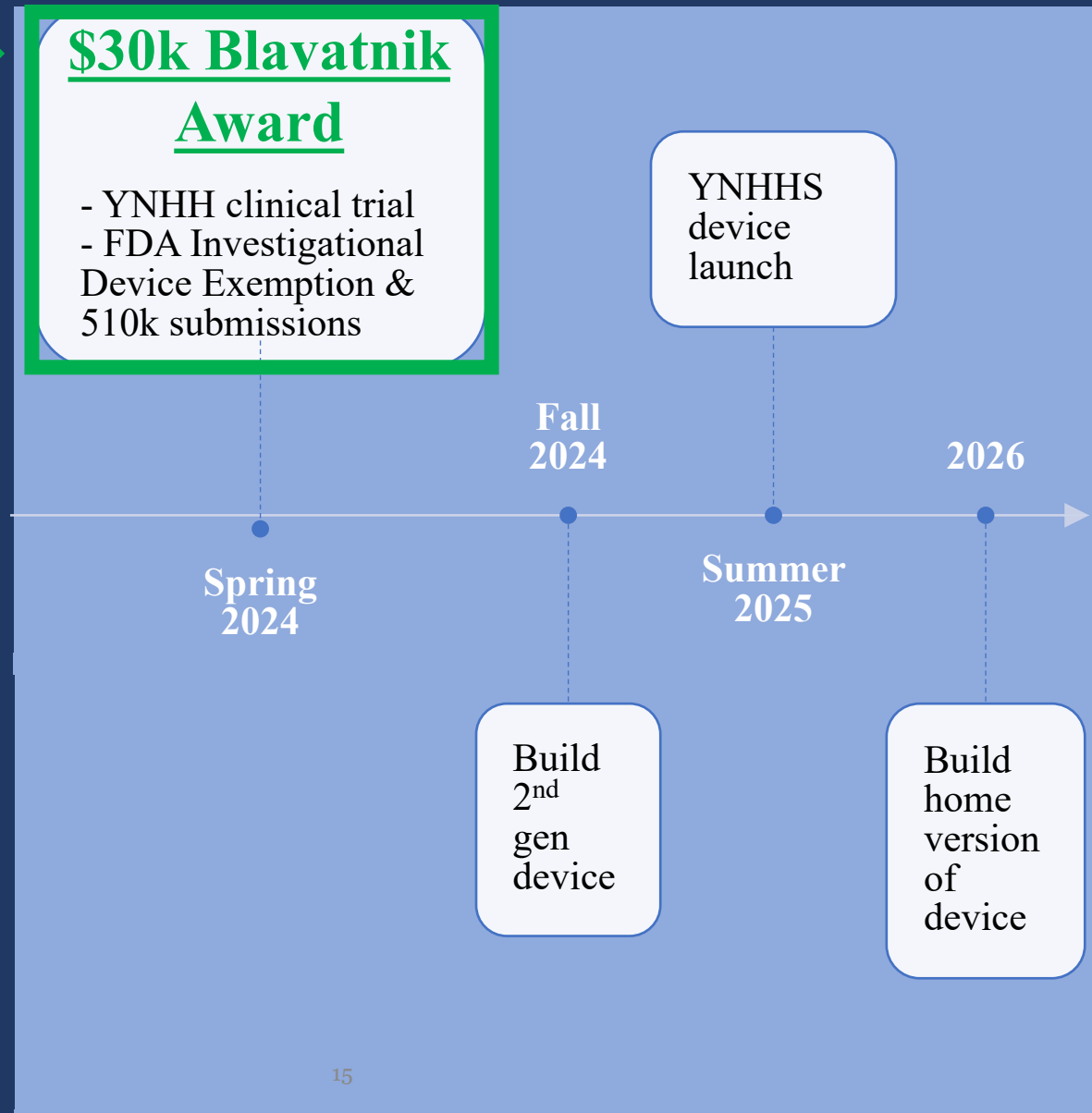
Build 2<sup>nd</sup> gen device

Build home version of device



# \$30k Blavatnik Award Enables FDA Approval for PCDD

2024 Milestone	Cost
Complete clinical trial at YNHH (funds to support research & nursing staff)	\$20k
Complete FDA Q-submission to determine regulatory strategy	\$5k
FDA 510(k) application fee	\$5k



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# Unit Economics Show \$1M Savings with 380 Patients

Each PCDD saves ~\$2,634 or 35% compared to pills



	Hospital Stay <sup>1</sup>	Nursing <sup>2</sup>	Pharmacy <sup>2</sup>	Medicine <sup>3</sup>	Unit Device Cost <sup>4</sup>	Patient Satisfaction <sup>5</sup>	Risk of Increased Healthcare costs <sup>6</sup>	Overhead Costs <sup>7</sup>	Total
Pills (Status Quo)	\$4.4K	\$1.3K	\$60	\$10	\$10	n/a	1.28x	\$50	\$7,463
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**Assumptions:** 1. Mean cost of \$4,383 & 4.35 day length of stay (LOS) for opioid-related hospitalization (PMID: 30584350), ~3 day LOS for PCDD

2. Bureau of Labor Statistics hourly nurse and pharmacy costs (Nursing: \$37/hr for 24 hrs for 4.35 vs. 3 days; Pharmacy: \$37/hr for 1 vs. 5 hrs)

3. Estimated using GoodRx pricing for 40 hydromorphone tablets and 120mL hydromorphone oral solution

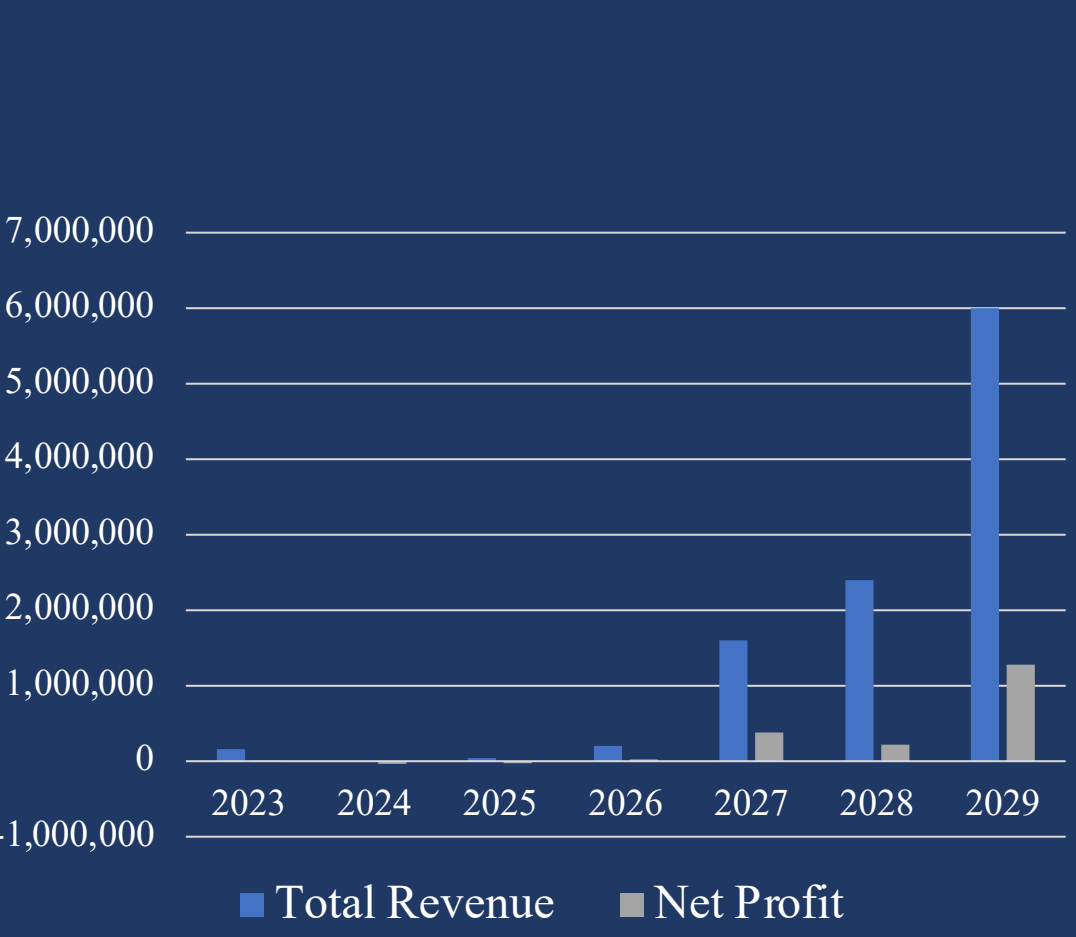
4. Estimated unit cost from \$22,999 cost of BD's automatic pill dispensing Pyxis machine vs. PCDD

5. 4% cost savings from 2018 study delivering integrative medicine to hospitalized patients (PMID: 29474095)

6. Estimated from 28% increased costs of Opioid Use Disorder (OUD) (PMID: 29764482) & 4% OUD prevalence in the US (PMID: 35783994)

7. Estimated unit cost to train nurses and pharmacists on the automatic pill dispensing Pyxis machine vs. PCDD

# Financials: PCDD to Earn \$1.2M in 2029 Across the Northeast



	2023	2024	2025	2026	2027	2028	2029
<b>Expenses</b>							
1st Contract (30 prototypes)	120,000						
Regulatory: Phase 1	30,000						
Regulatory: Phase 2 (510K)		30,000					
Costs of Goods Sold (\$300/unit)			30,000	150,000	1,200,000	1,800,000	4,500,000
<b>Total Expenses</b>	<b>150,000</b>	<b>30,000</b>	<b>30,000</b>	<b>150,000</b>	<b>1,200,000</b>	<b>1,800,000</b>	<b>4,500,000</b>
<b>Revenue</b>							
YNHHS Innovation Award 2022	150,000						
Anesthesia Pitch Award	1,000						
Yale SOM Award	7,500						
Units sold (\$400/unit)			100	500	4,000	6,000	15,000
Sales Revenue			\$40,000	\$200,000	\$1,600,000	\$2,400,000	\$6,000,000
<b>Total Revenue</b>	<b>158,500</b>	<b>0</b>	<b>40,000</b>	<b>200,000</b>	<b>1,600,000</b>	<b>2,400,000</b>	<b>6,000,000</b>
<b>Net Profit</b>	<b>8,500</b>	<b>-38,500</b>	<b>-28,500</b>	<b>21,500</b>	<b>378,500</b>	<b>221,500</b>	<b>1,278,500</b>

# PCDD 5-Year Financial Projection

	2023	2024	2025	2026	2027
<b>Expenses</b>					
Contract Manufacturer: Initial contract for 30 prototypes to be used for initial pilot study	120,000				
Contract Manufacturer: 2nd contract to produce prototypes for phase II RCT study at limited delivery networks of YNHH: YSC and SRC only		200,000			
Contract Manufacturer: 3rd contract to produce first lot of products for market YNHH system wide (estimated 100 units)			300,000		
Regulatory: Phase 1 (Initial Regulatory Plan)	30,000				
Regulatory: Phase 2 (510K submission to FDA)		60,000			
Legal: Intellectual Property		20,000	20,000	20,000	20,000
Salary for 10 Personnel				500,000	500,000
Clinical Trial at YNHH	75,000	120,000			
Prototyping Supplies	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000
Form and continue LLC	\$720	680	680	680	680
<b>Total Expenses</b>	<b>230,720</b>	<b>405,680</b>	<b>325,680</b>	<b>525,680</b>	<b>525,680</b>
<b>Revenue (awards, grants, etc.)</b>					
YNHHS Innovation Award 2022	150,000				
Anesthesia Conference Shark Tank 2022 Award	1,000				
<b>Units sold (\$200 per unit)</b>				<b>100</b>	<b>200</b>
Sales Revenue				\$20,000	\$40,000
<b>Total Revenue</b>	<b>151,000</b>	<b>0</b>	<b>0</b>	<b>20,000</b>	<b>40,000</b>
<b>Expenses Less Revenue</b>	<b>79,720</b>	<b>405,680</b>	<b>325,680</b>	<b>505,680</b>	<b>485,680</b>
<b>Total Start-Up Costs</b>					<b>2,013,440</b>

# PCDD to Submit FDA Class 2 Regulatory Approval

Classification  
Pathway

FDA Background  
Research

FDA  
Application

FDA  
Registration

Comments

**Class 1: Low Risk of  
Illness or Injury**

75% exempt from  
approval

Research and  
Device  
Classification

Exempt from  
Approval  
Process

Register the  
Establishment  
and List the  
Device

- Least regulatory scrutiny
- Low risk devices require limited review

**Class 2:  
Moderate Risk of  
Illness or Injury**

Majority require  
510(k)

Research and  
Device  
Classification

510(k)  
Pre-market  
Notification  
Application

Register the  
Establishment  
& List the  
Device

- Moderate regulatory scrutiny
- If predicate (similar) device exists on the market, process is smoother

**Class 2: De Novo**

Required if no  
predicate devices

Research and  
Device  
Classification

510(k) Pre-market  
Notification  
Application

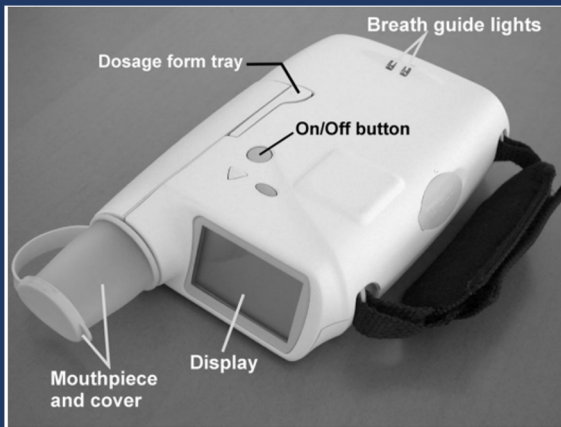
De Novo Device  
Request

Register the  
Establishment  
and List the  
Device

- Moderate regulatory scrutiny
- If no predicate, additional filing requirements needed

**Q-Submission needed (feedback  $\leq 75$  days) to determine regulatory path**

# \$58 Billion Global Pain Management Market



**2003 Inhalation:**  
AERx (Aradigm)



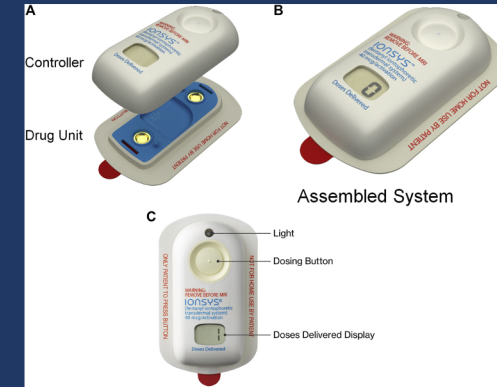
**2006 Intranasal:**  
Rylomine  
(Morphine)



**2007 Inhalation:**  
AeroLEF for  
Fentanyl



**2015 Sublingual**  
Sufentanil Tablet System  
(SSTS, 1st Gen, Zalviso)



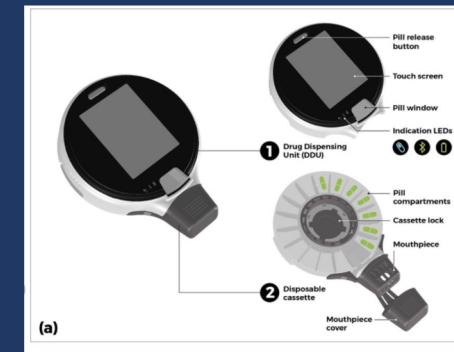
**2016 Transdermal:**  
Fentanyl  
Iontophoretic  
System (FITS)



**2017 Oral:**  
PCoA Acute (Dosentrx)



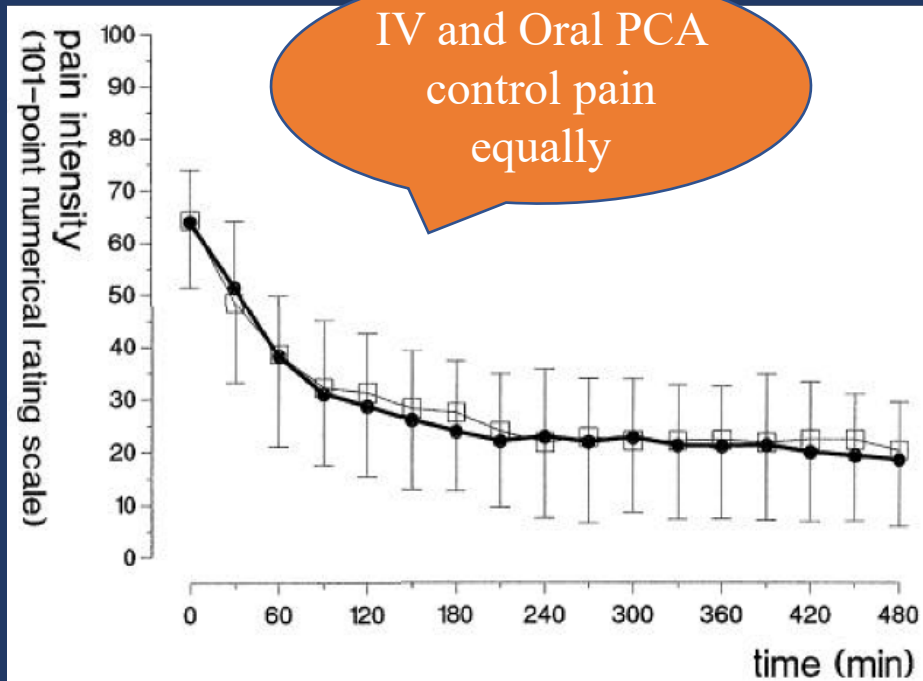
**2017 Oral:**  
Avancen Corporation  
Medication on Demand (MOD)



**2018 Oral:**  
ReX (Dosentrx)  
**Trend Towards Oral PCAs**



# Oral Liquid Format is Advantageous

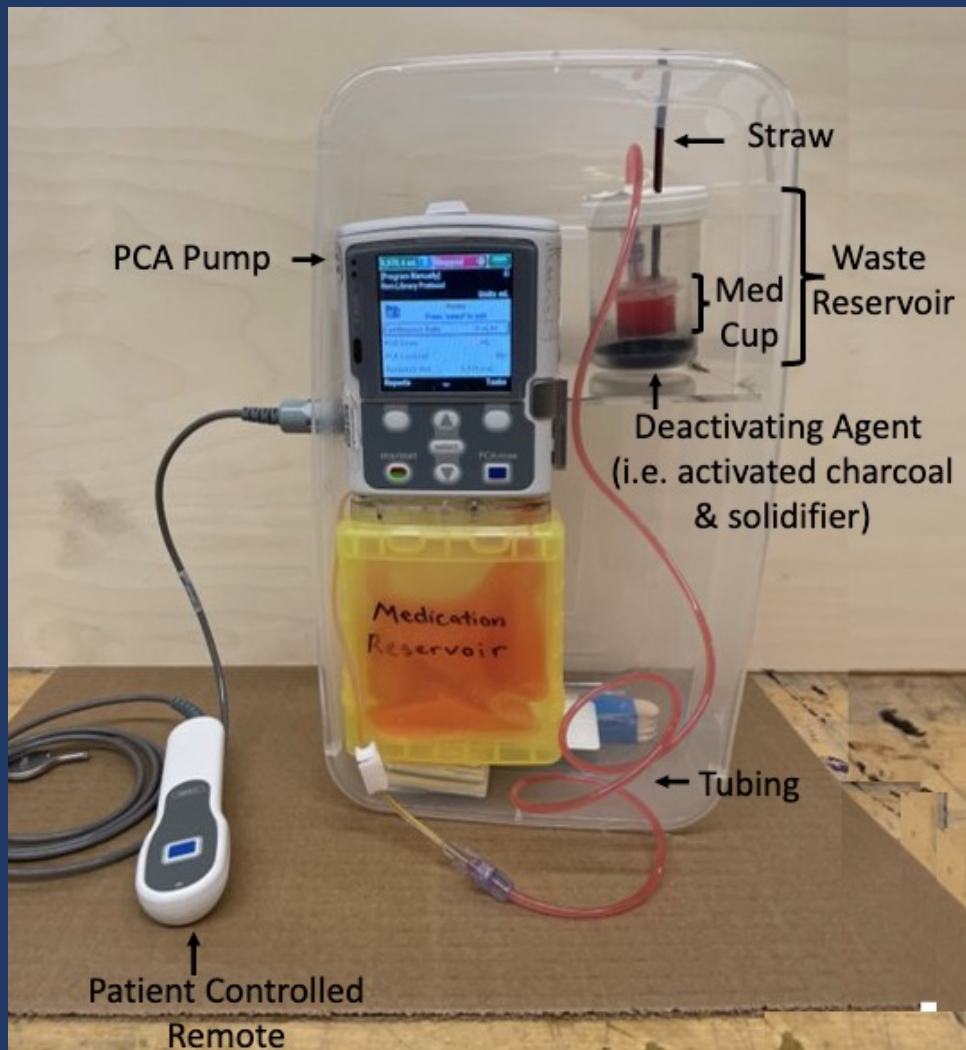


**Figure 1.** Postoperative course of pain intensity over 480 min, evaluated every 30 min with the aid of a 101-point numerical rating scale. Patient-controlled oral analgesia group (●), patient-controlled IV analgesia group (□).

## PCDD design principals

- Oral liquid opioids exist for every opioid pill
- Similar bioavailability
- Patients like liquid format
- Pharmacy is very experienced with oral liquid opioids

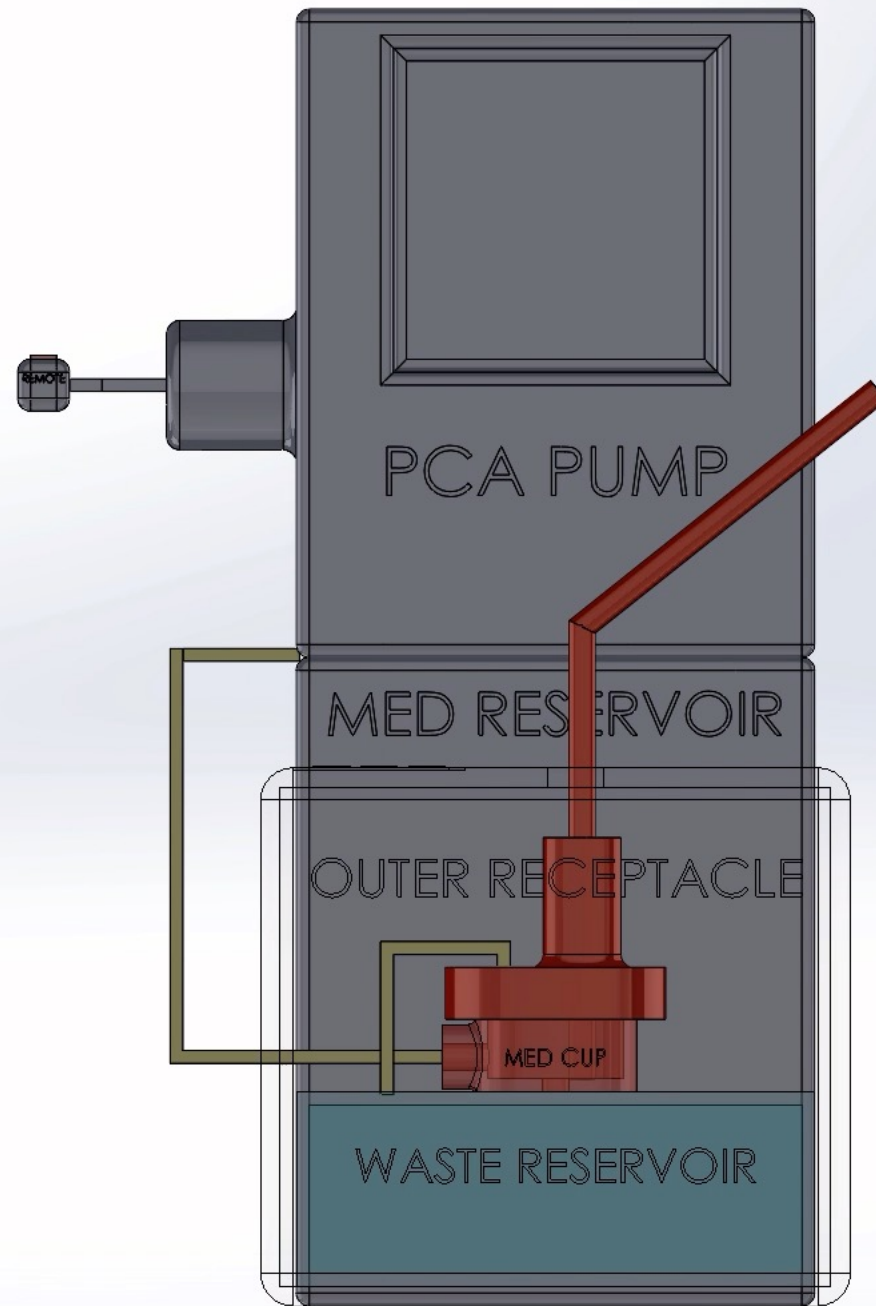
# PCDD Safety Features & Clinical Benefits



- Attaches to any PCA pump
- Tamperproof
- Secure straw and cup
- Empowers patient for improved outcomes
- Lowers side effects: overdose/euphoria
- Reduces nursing workload
- Digitizes opioid consumption in hospital
- Accurate estimation of discharge prescription need
- Deactivates left over medication

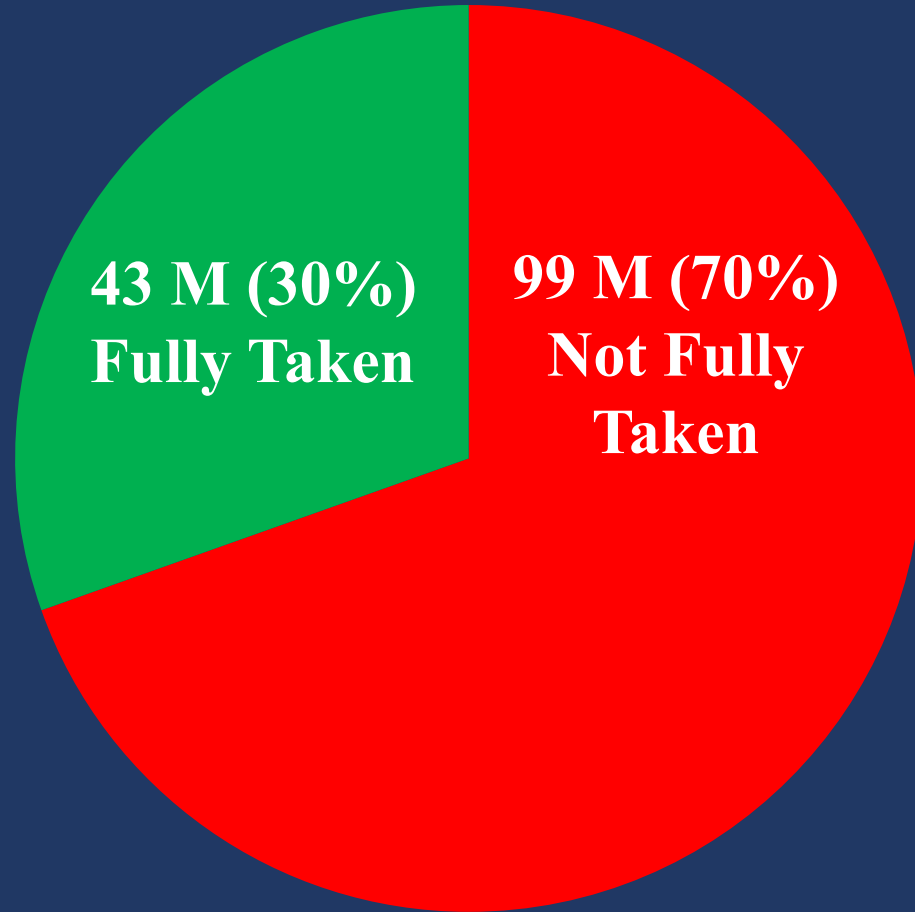
# PCDD Tracks Medication at Home





# PCDD Mitigates Diversion of Prescription Drugs

2020 opioid prescriptions dispensed:



>50% of misused prescribed opioids were obtained from family & friends

# PCDD Improves Equity in Pain Management for African Americans, Low SES, and Females

**Average Annual Percentage Increase of Opioid-Involved Overdose Deaths in the U.S. from 2012-2018**

